John E. Flaherty
Ravin R. Patel
McCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Counsel for Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, and Zeneca Inc.

Einar Stole
Ed Rippey
COVINGTON & BURLING LLP
1201 Pennsylvania Ave., NW
Washington, DC 20004
(202) 662-6000

Of Counsel for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC.,

Plaintiffs,

v.

ACTAVIS LABORATORIES FL, INC., and ACTAVIS PHARMA, INC.,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, and Zeneca Inc. (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Actavis Laboratories FL, Inc. ("Actavis Florida"), and Actavis Pharma, Inc. ("Actavis Pharma"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 207079 filed by or for the benefit of Actavis Florida and Actavis Pharma (collectively, "Defendants" or "Actavis") with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' NEXIUM® pharmaceutical products that are sold in the United States.

THE PARTIES

2. Plaintiff AstraZeneca AB ("AZ AB") is a corporation operating and existing under the laws of the Sweden, with its principal place of business at Södertälje, Sweden. AstraZeneca AB was a corporate name change from Astra Aktiebolaget.

3. Plaintiff Aktiebolaget Hässle is a corporation organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden.

4. Plaintiff AstraZeneca LP ("AZ LP") is a limited partnership operating and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. AZ LP holds approved New Drug Application ("NDA") No. 021153 from the FDA for a delayed-release esomeprazole magnesium formulation that it sells under the name NEXIUM®.

5. Plaintiff Zeneca Inc. ("Zeneca") is a Delaware corporation having its principal place of business at Wilmington, Delaware. Zeneca has exclusive rights in the United States to

market and sell products covered by United States Patent Nos. 5,714,504; 6,369,085; 7,411,070; and 8,466,175.

6. On information and belief, Actavis Florida is a corporation organized and existing under the laws of Florida, having its principal place of business at 4955 Orange Drive, Davie, Florida 33314. On information and belief, Actavis Florida is in the business of, inter alia, developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products throughout the United States, including within this district.

7. On information and belief, Actavis Florida is a wholly-owned subsidiary of Andrx Corporation (a Delaware corporation, having its principal place of business at 4955 Orange Drive, Davie, Florida 33314), which is a wholly-owned subsidiary of Actavis, Inc. (a Nevada corporation, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054).

8. On information and belief, Actavis Pharma is a corporation organized and existing under the laws of Delaware, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Actavis Pharma is in the business of, inter alia, selling and distributing generic copies of branded pharmaceutical products in New Jersey and throughout the United States, including some that are manufactured by Actavis Florida and/or for which Actavis Florida is the named applicant of the approved ANDAs.

9. On information and belief, Actavis Pharma is a wholly owned subsidiary of Actavis, Inc.

BACKGROUND

The NDA

10. AZ LP is the holder of NDA No. 21153 for NEXIUM® Esomeprazole Magnesium Delayed-Release Capsules, in 20 mg and 40 mg dosage forms. NEXIUM® is a prescription drug approved for use to relieve the symptoms of acid reflux disease and treat erosive esophagitis. Esomeprazole magnesium trihydrate is the active ingredient in NEXIUM®.

The Patents-in-Suit

11. United States Patent No. 5,714,504 ("the '504 patent"), entitled "Compositions," was duly and legally issued by the United States Patent and Trademark Office ("the USPTO") on February 3, 1998 to Astra Aktiebolag upon assignment from inventors Per Lennart Lindberg and Sverker Von Unge. The claims of the '504 patent are directed to, *inter alia*, pharmaceutical formulations comprising alkaline salts of esomeprazole (including esomeprazole magnesium) and methods of using the claimed salts. A true and correct copy of the '504 patent is attached as Exhibit A.

12. Plaintiff AZ AB has been and still is the owner of the '504 patent. The '504 patent will expire on February 3, 2015, and pediatric exclusivity relating to the '504 patent expires on August 3, 2015.

13. United States Patent No. 6,369,085 ("the '085 patent"), entitled "Form of S-Omeprazole," was duly and legally issued by the USPTO on April 9, 2002 to AZ AB, upon assignment from the inventors Hanna Cotton, Anders Kronstrom, Anders Mattson, and Eva Möller. The '085 patent claims, *inter alia*, magnesium salts of esomeprazole trihydrate, pharmaceutical compositions comprising the claimed salts, methods of treatment using the

claimed salts, and processes for preparing the claimed salts. A true and correct copy of the ’085 patent is attached as Exhibit B.

14. Plaintiff AZ AB has been and still is the owner of the ’085 patent. The ’085 patent will expire on May 25, 2018, and pediatric exclusivity relating to the ’085 patent expires on November 25, 2018.

15. United States Patent No. 7,411,070 (“the ’070 patent”), entitled “Form of S-omeprazole,” was duly and legally issued by the USPTO on August 12, 2008 to AZ AB upon assignment from inventors Hanna Cotton, Anders Kronstrom, Anders Mattson, and Eva Moller. The claims of the ’070 patent are directed to, *inter alia*, magnesium salts of esomeprazole trihydrate and processes for preparing the claimed salts. A true and correct copy of the ’070 patent is attached as Exhibit C.

16. Plaintiff AZ AB has been and still is the owner of the ’070 patent. The ’070 patent will expire on May 25, 2018, and pediatric exclusivity relating to the ’070 patent expires on November 25, 2018.

17. United States Patent No. 8,466,175 (“the ’175 patent”), entitled “Form of S-omeprazole,” was duly and legally issued by the USPTO on June 18, 2013 to AZ AB upon assignment from inventors Hanna Cotton, Anders Kronstrom, Anders Mattson, and Eva Moller. The claims of the ’175 patent are directed to, *inter alia*, methods of treating Heliobacter infections comprising administration of magnesium salts of esomeprazole trihydrate. A true and correct copy of the ’175 patent is attached as Exhibit D.

18. Plaintiff AZ AB has been and still is the owner of the ’175 patent. The ’175 patent will expire on May 25, 2018, and pediatric exclusivity relating to the ’175 patent expires on November 25, 2018.

The ANDA

19. On information and belief, Actavis Florida filed ANDA No. 207079 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, importation, offer for sale, and sale in the United States of esomeprazole magnesium delayed-release capsules, 20 mg ("the ANDA Product"), which are generic versions of Plaintiffs' NEXIUM® Esomeprazole Magnesium Delayed-Release Capsules, in a 20 mg dosage form.

20. By letter dated November 4, 2014 (the "ANDA Notice Letter"), Actavis Florida notified Plaintiffs that Actavis Florida had filed ANDA No. 207079 seeking approval to market the ANDA Product and that Actavis Florida was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95.

JURISDICTION AND VENUE

21. Subject matter jurisdiction over this action is proper pursuant to the provisions of Title 28, United States Code, Sections 1331 and 1338(a).

22. On information and belief, Defendant Actavis Pharma is a corporation organized and existing under the laws of Delaware, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

23. On information and belief, Actavis Florida, either directly or through one or more of its wholly owned subsidiaries and/or agents, develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within the judicial district.

24. On information and belief, Actavis Pharma, with the assistance and/or at the direction of Actavis Florida, develops, manufactures, distributes, markets, offers to sell, and sells

generic drug products for sale and use throughout the United States, including within the judicial district.

25. On information and belief, Defendants are in the business of developing, formulating, manufacturing, marketing, offering to sell, selling, and commercializing pharmaceutical products.

26. On information an belief, Defendants acted in concert to develop the ANDA Product and to seek approval from the FDA to sell the ANDA Product throughout the United States, including within this judicial district.

27. On information and belief and as stated in the ANDA Notice Letter, Actavis Florida prepared and filed ANDA No. 207079.

28. On information and belief and as stated in the ANDA Notice Letter, the FDA received ANDA No. 207079 from Actavis Florida.

29. On information and belief by virtue of, inter alia, Actavis Florida's relationship with Actavis Pharma in connection with the preparation and/or filing of ANDA No. 207079 and the sales-related activities of Defendants in New Jersey, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of New Jersey, this Court has personal jurisdiction over Actavis Florida.

30. On information and belief, by virtue of, inter alia, Defendants' continuous and systematic contacts with New Jersey, including but not limited to the above-described contacts, and the actions on behalf of Defendants in connection with ANDA No. 207079, this Court has personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with New Jersey law.

31. Venue is proper in this District pursuant to the provisions of Title 28, United States Code, Sections 1391(c) and (d), and 1400 (b).

COUNT 1: INFRINGEMENT OF THE '504 PATENT

32. Plaintiffs incorporate by reference paragraphs 1-31 of this Complaint as if fully set forth herein.

33. On information and belief, Defendants submitted ANDA No. 207079 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market the ANDA Product in the United States before the expiration of the '504 patent.

34. By their ANDA Notice Letter, Defendants informed Plaintiffs that they had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '504 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product.

35. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 207079 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product before the expiration of the '504 patent constitutes infringement of one or more claims of the '504 patent, either literally or under the doctrine of equivalents.

36. On information and belief, the ANDA Product, if approved by the FDA, will be administered to human patients in a therapeutically effective amount to inhibit gastric acid secretion and for the treatment of gastrointestinal inflammatory diseases. On information and belief, this administration will occur at Defendants' active behest and with their intent, knowledge, and encouragement. On information and belief, Defendants will actively encourage,

aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '504 patent.

37. On information and belief, the ANDA Product is a component of the formulations patented in the '504 patent, is a material for use in practicing the methods patented in the '504 patent, constitutes a material part of those inventions, is especially made or especially adapted for use in an infringement of the '504 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA Product is so made or so adapted. On information and belief, Defendants are aware that the ANDA Product, if approved, will be used in contravention of Plaintiffs' rights under the '504 patent.

38. The ANDA Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding all defenses, does not allege non-infringement of any claims of the '504 patent. By not alleging non-infringement, Defendants admit that the ANDA Product meets all limitations of the claims of the '504 patent.

39. The ANDA Notice Letter does not allege and does not address unenforceability of the '504 patent. By not addressing unenforceability of the '504 patent in their 2013 Notice Letter, Defendants admit that the '504 is enforceable.

40. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT 2: INFRINGEMENT OF THE '085 PATENT

41. Plaintiffs incorporate by reference paragraphs 1-31 of this Complaint as if fully set forth herein.

42. On information and belief, Defendants submitted ANDA No. 207079 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market the ANDA Product in the United States before the expiration of the '085 patent.

43. By their ANDA Notice Letter, Defendants informed Plaintiffs that they had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '085 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product.

44. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 207079 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product before the expiration of the '085 patent constitutes infringement of one or more claims of the '085 patent, either literally or under the doctrine of equivalents.

45. On information and belief, the ANDA Product, if approved by the FDA, will be administered to human patients in a therapeutically effective amount to treat gastric acid related conditions. On information and belief, this administration will occur at Defendants' active behest and with their intent, knowledge, and encouragement. On information and belief, Defendants will actively encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '085 patent.

46. On information and belief, the ANDA Product is a component of the compounds patented in the '085 patent, is a material for use in practicing the methods patented in the '085 patent, constitutes a material part of those inventions, is especially made or especially adapted for use in an infringement of the '085 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are

aware that the ANDA Product is so made or so adapted. On information and belief, Defendants are aware that the ANDA Product, if approved, will be used in contravention of Plaintiffs' rights under the '085 patent.

47. The ANDA Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding all defenses, does not allege invalidity or unenforceability of any claims of the '085 patent. By not alleging invalidity or unenforceability, Defendants effectively admit that the '085 patent is both valid and enforceable.

48. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT 3: INFRINGEMENT OF THE '070 PATENT

49. Plaintiffs incorporate by reference paragraphs 1-31 of this Complaint as if fully set forth herein.

50. On information and belief, Defendants submitted ANDA No. 207079 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market the ANDA Product in the United States before the expiration of the '070 patent.

51. By their ANDA Notice Letter, Defendants informed Plaintiffs that they had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '070 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product.

52. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 207079 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product before the expiration of the '070

patent constitutes infringement of one or more claims of the '070 patent, either literally or under the doctrine of equivalents.

53. On information and belief, the ANDA Product, if approved by the FDA, will be administered to human patients at Defendants' active behest and with their intent, knowledge, and encouragement. On information and belief, Defendants will actively encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '070 patent.

54. On information and belief, the ANDA Product contains a component of the compound patented in the '070 patent, is a material for use in practicing the methods patented in the '070 patent, constitutes a material part of those inventions, is especially made or especially adapted for use in an infringement of the '070 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA Product is so made or so adapted. On information and belief, Defendants are aware that the ANDA Product, if approved, will be used in contravention of Plaintiffs' rights under the '070 patent.

55. The ANDA Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding all defenses, does not allege invalidity or unenforceability of any claims of the '070 patent. By not alleging invalidity or unenforceability, Defendants effectively admit that the '070 patent is both valid and enforceable.

56. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT 4: INFRINGEMENT OF THE '175 PATENT

57. Plaintiffs incorporate by reference paragraphs 1-31 of this Complaint as if fully set forth herein.

58. On information and belief, Defendants submitted ANDA No. 207079 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market the ANDA Product in the United States before the expiration of the '175 patent.

59. By their ANDA Notice Letter, Defendants informed Plaintiffs that they had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '175 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product.

60. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 207079 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product before the expiration of the '175 patent constitutes infringement of one or more claims of the '175 patent, either literally or under the doctrine of equivalents.

61. On information and belief, the ANDA Product, if approved by the FDA, will be prescribed and administered to human patients in a therapeutically effective amount to inhibit gastric acid secretion and for the treatment of gastrointestinal inflammatory disease, including Heliobacter infection. On information and belief, this administration will occur at Defendants' active behest and with their intent, knowledge, and encouragement. On information and belief, Defendants will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '175 patent.

62. The ANDA Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding all defenses, does not allege invalidity or unenforceability of any claims of the '175 patent. By not alleging invalidity or unenforceability, Defendants effectively accept the statutory presumption that the '175 patent is both valid and unenforceable.

63. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the claims of the '504, '085, '070, and '175 patents are valid and enforceable;

B. A judgment that the submission of ANDA No. 207079 by Defendants infringes one or more claims of each of the '504, '085, '070, and '175 patents under 35 U.S.C. § 271(e)(2);

C. A judgment providing that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Defendants' ANDA No. 207079 shall be no earlier than the latest expiration date of the patents-in-suit and any additional periods of exclusivity;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants, and all persons acting in concert with any of them, from making, using, selling, offering to sell, or importing the esomeprazole magnesium product described in Defendants' ANDA No. 207079 prior to the latest expiration of the patents-in-suit and any additional periods of exclusivity;

E. Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court may deem just and proper.

Dated: December 17, 2014

Respectfully submitted,

s/ John E. Flaherty

John E. Flaherty
Ravin R. Patel
McCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Counsel for Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, and Zeneca Inc.

Einar Stole
Ed Rippey
COVINGTON & BURLING LLP
1201 Pennsylvania Ave., NW
Washington, DC 20004
(202) 662-6000

Of Counsel for Plaintiffs

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is related to the subject matter of the following actions:

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. MYLAN LABORATORIES LTD. and MYLAN, INC.*, C.A. No. 3:12-cv-01378-JAP-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. WATSON LABORATORIES, INC. – FLORIDA*, C.A. No. 3:13-cv-01669-JAP-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. WOCKHARDT LIMITED and WOCKHARDT USA LLC*, C.A. No. 3:13-cv-04854-JAP-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA USA Inc.*, C.A. No. 3:13-cv-7298-JAP-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. KREMERS URBAN PHARMACEUTICALS, KREMERS URBAN DEVELOPMENT CO., and KREMERS URBAN LLC*, C.A. No. 3:13-cv-7299-JAP-TJB (District of New Jersey)

- *ASTRAZENECA AB; AKTIEBOLAGET HÄSSLE; ASTRAZENECA LP; KBI INC.; and KBI-E INC. v. ZYDUS PHARMACEUTICALS (USA) INC., and CADILA HEALTHCARE LTD. (dba ZYDUS CADILA)*, C.A. No. 3:13-cv-4782-JAP-TJB (District of New Jersey)

- *ASTRAZENECA AB; AKTIEBOLAGET HÄSSLE; ASTRAZENECA LP; and ZENECA INC. v. ACTAVIS LABORATORIES FL, INC. and ACTAVIS PHARMA, INC.*, 3:14-cv-07263-MLC-TJB (District of New Jersey, November 20, 2014)

Date: December 17, 2014

By: *s/ John E. Flaherty*

John E. Flaherty
Ravin R. Patel
McCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Counsel for Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, and Zeneca Inc.

Einar Stole
Ed Rippey
COVINGTON & BURLING LLP
1201 Pennsylvania Ave., NW
Washington, DC 20004
(202) 662-6000

Of Counsel for Plaintiffs